

REMARKS

Claim 1 is amended to incorporate the subject matter of claim 7 and certain subject matter of claim 25. Claim 25 is amended to incorporate the subject matter of claim 32. Claims 7, 32, and 57-59 are canceled by this amendment.

Priority

Applicants have cancelled claim 57. Certified English translations of the priority documents will be filed in a supplemental response.

Drawings

As requested by the Examiner, typographical errors in the drawings are corrected by this amendment.

Claim Objections

Claims 8 and 33 are objected to because the Examiner alleges that the VSV-G pseudotype confers no heritable structural feature onto the transgenic bird. Applicants contend that the VSV-G pseudotype does confer a structural feature onto the transgenic bird. When the retrovirus vector is a VSV-G pseudo type one, the birds can be infected with a high concentration of the virus. This results in high gene induction efficiency, which results in the transgenic bird producing greater quantities of the exogenous protein. These greater quantities of the exogenous protein are a structural feature of the transgenic bird.

Claim Rejections Under 35 USC 112

Claims 42-45 are rejected under 35 USC 112, second paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Without conceding to the propriety of this rejection, in order to expedite prosecution, claims 42-45 have been amended to change “mating type allogeneic” to “allogeneic.” Claim 45 has also been amended to specify that there are two birds mating with each other. Support for this amendment can be found on lines 2-16 of page 21 in the specification. By these amendments, Applicants respectfully submit that claims 42-45 are now even more fully compliant with 35 USC 112, second paragraph.

With respect to claim 48, the limitation reciting that the transgenic bird is “produced by the method according to Claim 42” unambiguously indicates that this transgenic bird is not the G0 transgenic chimera bird, but an offspring of the G0 transgenic chimera bird.

Claim Rejections Under 35 USC 102

Claim 57 is rejected under 35 USC 102(b) as being allegedly anticipated by Harvey et al. (Poultry Science 81(2):202-212; Feb. 2002). Claim 57 is cancelled by this amendment, thus rendering this rejection moot.

In the pending Office Action, ¶¶ 4-6 apply Ivarie et al. (U.S. Patent No. 6,730,822), Rapp et al. (Publication No. 2002/0108132), and Rapp et al. (Publication No. 2003/0126629) in a rejection under 35 USC 102 against the claims specified in ¶¶ 4-6.

Claim 25 is deemed to be free of these references. As such, claim 1 is amended to incorporate the limitation of claim 25 specifying that the infection of the early embryo occurs after and exclusive of a blastodermal period immediately after the spawning with a replication-defective retrovirus vector.

None of the above references disclose this particular time-frame for embryo infection. For at least these reasons, independent claims 1 and 25, and all claims that depend therefrom, are not anticipated by the references applied in ¶¶ 4-6 of the pending Office Action.

Claim Rejections Under 35 USC 103

In the pending Office Action, ¶¶ 7-10 apply various combinations of Ivarie et al. (U.S. Patent No. 6,730,822), Rapp et al. (Publication No. 2002/0108132), Chad et al. (Curr. Op. Biotechnology 12(2):188-194; 2001); Guild et al. (J. Virology 62(10):3795-3801; 1988); and Powers et al. (J. Immunol. Methods 251:123-135; 2001) in a rejection under 35 USC 103 against the claims specified in ¶¶ 7-10.

None of these references teaches or suggests the particular time-frame for embryo infection, as recited by claims 1 and 25. Thus, without conceding that any of the various combinations of these references suggested by the pending Office Action is proper, none of the suggested combinations could include this feature of claims 1 and 25.

Furthermore, none of these references recognizes the unexpected effect imparted by infecting the early embryo in this particular time-frame. Through a series of experiments in which the vector was introduced at different times after fertilization, the inventors have discovered that the effect of gene silencing is time-dependent, with the gene silencing effect becoming diminished with later introduction of the vector. This effect is demonstrated in the specification at Example 5 and FIGS. 2 and 3 showing that the β -galactosidase activity differs considerably depending upon when the vector containing the β -galactoside gene was introduced. In particular, infecting the embryo at a time after and exclusive of a blastodermal period immediately after the spawning with a replication-defective retrovirus vector resulted in a dramatically increased expression of the intended gene. As such, claims 1 and 25 recites this specific time-frame for infecting the embryo, which the inventors have discovered to be particularly effective in minimizing the effects of gene silencing.

Without a recognition of this unexpected effect, there is no reason to modify any of the above references to infect the embryo after and exclusive of a blastodermal period immediately after the spawning with a replication-defective retrovirus vector, as recited by claims 1 and 25. For at least these reasons, claims 1 and 25, and all claims that depend therefrom, are patentable over the references applied in ¶¶ 7-10 of the pending Office Action.

In the pending Office Action, ¶¶ 11-15 apply various combinations of Mizuarai et al. (J. Biochem. 129:125-132; Jan. 2001), Ivarie et al. (U.S. Patent No. 6,730,822), Schatten et al. (Publication No. 2003/0221206); Guild et al. (J. Virology 62(10):3795-3801; 1988); Rapp et al. (Publication No. 2002/0108132); and Powers et al. (J. Immunol. Methods 251:123-135; 2001) in a rejection under 35 USC 103 against the claims specified in ¶¶ 11-15 of the pending Office Action.

None of these references teaches or suggests the particular time-frame for embryo infection as recited by claim 25. Thus, without conceding that any of the various combinations of these references suggested by the pending Office Action is proper, none of the suggested combinations could include this feature of claim 25.

Furthermore, none of these references recognizes the unexpected effect imparted by infecting the early embryo in this particular time-frame, as explained above. Without a recognition of this unexpected effect, there is no reason to modify any of the above references to

infect the embryo after and exclusive of a blastodermal period immediately after the spawning with a replication-defective retrovirus vector. For at least these reasons, claim 25, and all claims that depend therefrom, are patentable over the references applied in ¶¶ 11-15 of the pending Office Action.

Double Patenting

In the pending Office Action at ¶ 16, the specified claims are provisionally rejected on the ground of non-statutory obviousness type double patenting over claims 6-14 and 17-22 of copending Application No. 10/569,268 (application number corrected). The claims in Application No. 10/569,268 recites the use of a lentivirus vector, and especially an HIV virus. In contrast, amended claim 1 of the present application recites using a Moloney murine leukemia virus. A person of ordinary skill in the art would know that a lentivirus has different characteristics than a pandemic retrovirus such as Moloney murine leukemia virus. Thus, Applicants respectfully submit that the claims specified in ¶ 16 of the pending Office Action are patentable over Application No. 10/569,268.

In the pending Office Action at ¶ 17, the specified claims are provisionally rejected on the ground of non-statutory obviousness type double patenting over claims 1-30 of copending Application No. 10/585,693. As these rejections are provisional, Applicants respectfully request that this rejection be held in abeyance until this is the only remaining rejection in this application.

CONCLUSION

It is respectfully submitted that the present application is now in condition for allowance, which action is respectfully requested. The Examiner is invited to contact Applicants' representative to discuss any issue that would expedite allowance of the subject application.

Any fees for extension(s) of time or additional fees are required in connection with the filing of this response, such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and the Commissioner is authorized to charge any such required fees or to credit any overpayment to Kenyon & Kenyon's Deposit Account No. 11-0600.

Respectfully submitted,

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